

Poster Title:

Examples Of Systematic Validation For Biomarkers Of Cigarette Smoke Exposure

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Abstract:

In Clearing the Smoke Assessing the Science Base for Tobacco Harm Reduction, the Institute of Medicine (IOM) delineated its expectations for biomarker assay validation. The well-known analytical components of reproducibility, sensitivity, and selectivity are specifically mentioned as requirements for biomarker assay validation. In addition, this report also calls for the validation from the biological perspective; that is, evaluation of intra- and inter-individual and inter-population variations and dose response.

A pilot study focusing on biomarker measurement in a group of adult male and female smokers of 3.0 – 6.9 mg tar cigarettes and a corresponding group of adult non-smokers is currently underway. The rigorous analytical validation standards used to assess the chromatographic analyses developed are consistent with IOM guidelines. Precision, accuracy, carryover, recovery, linearity, limits of quantitation, and stability measures will be compared to previously established acceptance criteria. The extremely low concentrations of the selected biomarkers in biological matrices required that hyphenated techniques be used for many of the analyses. Complications in analytical validation due to the unavailability of both analyte-free matrix and alternate methods for matrix analysis for many of the biomarkers will be addressed. Specific instances where the validation exercise led to a modification of the analytical method will be described.